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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/031,087	02/26/1998	CHIH-SHENG CHIANG	054769-2001	8207

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EXAMINER	
TUNG, JOYCE	
ART UNIT	**PAPER NUMBER**
1637	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/22/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	09/031,087	CHIANG ET AL.	
	Examiner	Art Unit	
	Joyce Tung	1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 January 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *2-11 and 14-22* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *2-11 and 14-22* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *3/01/07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The applicant's response filed 1/18/07 to the Office action has been entered. Claims 2-11 and 14-22 are pending.

1. Claims 2-11, and 19-22 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Tyagi et al. (6,103,476, issued Aug. 15, 2000), in view of Diamond et al. (4,766,062, issued Aug. 23, 1988).

Tyagi et al. disclose assays for monitoring the progress of an amplification reaction. The probe can be present during synthesis. The presence of the probes improves the accuracy of the estimates of the target nucleic acid concentration (See column 22, lines 41-46 and lines 57-61). Other nucleic acid amplification schemes can be monitored, such as strand-displacement amplification (See column 23, lines 36-41). The polymerase is thermostable (See column 34, lines 60-67).

Tyagi et al. do not disclose the probe, which has the features, recited in claims 20, 22, and 3-10.

Diamond et al. disclose a diagnostic reagent containing a complex of a probe (See the Abstract). The probe has the same features as recited in claims 20, 22, and 3-10 (See column 6, lines 3-19, column 21, lines 15-52).

One of the ordinary skill in the art would have been motivated to apply the complex of the probe of Diamond et al. because as indicated by Diamond et al. the complex of the probe is used in solution as the reagent is mixed with a biological sample such that hybridization will occur (See column 7, lines 57-67) since monitoring nucleic acid amplification is always occurred

in solution and the labeled polynucleotide is stable, but reversible binding to the probe at a specific locus and has a label susceptible to detection, especially after displacement (See column 8, lines 55-60). It would have been prima facie obvious to apply the complex of the probe as taught by Diamond et al. for monitoring nucleic acid amplification.

The response discussed the unimolecular probe and the bimolecular probe of Tyagi et al. and the physiochemical rationale of using the bimolecular probe of Tyagi et al. which should be avoided for amplification reactions. However, the unimolecular probe is used in amplification (See column 6, lines 58-62) for monitoring the amplification (See column 22, lines 35-46). The features of the unimolecular probe of Tyagi (See fig. 3 and 5) have the same features as recited in the claims except that Tyagi et al. do not disclose that the probes are not equal in length. However, Diamond et al. disclose a complex of probes, which has a probe polynucleotide p and a labeled polynucleotide (See column 6, lines 3-19 and column 21, lines 15-32). The probe polynucleotide P and the labeled polynucleotide are not equal in length (See fig 3). One of the probes of Tyagi et al. is used in monitoring amplification reaction (See column 23, lines 36-41) and Diamond et al. disclose a complex of probes which has a probe polynucleotide p and a labeled polynucleotide (See column 6, lines 3-19 and column 21, lines 15-32) which are not equal in length (See fig 3). Thus, it would have been prima facie obvious to apply the complex of the probe as taught by Diamond et al. for monitoring nucleic acid amplification.

Regarding the physiochemical rationale of bimolecular probes, which should be avoided for amplification reactions, the physiochemical rationale discussed by Tyagi et al. (See column 3, lines 11-18) is not applicable to the bimolecular probe disclosed by Tyagi et al. because the bimolecular probe as discussed in column 3, lines 11-18 is different from the probes disclosed by

Tyagi et al.. Furthermore, the teachings of Tyagi et al. regarding the unimolecular probe or bimolecular probe read on the limitations of the probe recited in the claims because it is unclear what is the physical relation between the first probe and the second probe of the instant claims. Thus based upon the analysis above, the rejection is maintained.

2. Claims 14-18 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Tyagi et al. (6,103,476, issued Aug. 15, 2000), in view of Diamond et al. (4,766,062, issued Aug. 23, 1988) as applied to claims 2-11, and 19-22, further in view of Hiroaki et al. (EP 0461 863 A1).

The teachings of Tyagi et al. and Diamond et al. are set forth in section 7 above. Tyagi et al. and Diamond et al. do not disclose that the target polynucleotide comprises hepatitis C virus genome, the probe has the sequence of SEQ ID NO: 3 and 4 and the primer has the sequence of SEQ ID NO: 1 and 2.

Hiroaki et al. disclose a highly sensitive detection system for NANB hepatitis virus at its gene level and oligonucleotide primer used for the system (See pg. 2, lines 31-32). The NANB hepatitis is termed hepatitis C virus (HCV) (See pg. 2, lines 10-12). A nucleotide sequence of the 5' noncoding region from HC-J1 has been identified (See pg. 3. lines 4-32). The primers used in the highly sensitive detection system for HCV corresponding to the part of the 5' noncoding region of HCV are disclosed (See pg. 3, lines 38-42). The nucleotide of the 5' noncoding region comprises SEQ ID NO: 1 and 3 and the complementary sequence of SEQ ID NO 2 and base pair 1-17 of SEQ ID NO: 4 (See pg. 7, lines 11-21 and pg. 8, lines 15-19).

One of ordinary skill in the art would have been motivated to apply these nucleic acid sequences disclosed by Hiroaki et al. as probes and primers in the method of Tyagi et al. for the specific detection of the target polynucleotide, hepatitis C virus because these nucleic acid sequences provide a highly sensitive detection system for NANB hepatitis virus at its gene level (See pg. 2, lines 31-32). It would have been prima facie obvious to apply SEQ ID NO: 1 and 2 as

primers and SEQ ID NO: 3 and 4 as probes in the method of Heller et al. for the detection of the target polynucleotide, hepatitis C virus.

The response does not have a specific argument regarding the rejection. Based upon the analysis in section 1 above, with the same reasons, the rejection is maintained.

Summary

3. No claims are allowed.

4. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joyce Tung whose telephone number is (571) 272-0790. The examiner can normally be reached on Monday - Friday, 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571 272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Joyce Tung
March 8, 2007

KENNETH R. HORLICK, PH.D
PRIMARY EXAMINER

3/19/07